Public Comment Fall 2011

(2) From the Histocompatibility

Committee



Update CPRA



Synopsis

The purpose of this proposal is to update the frequencies used to calculate CPRA so it will better reflect current laboratory practices as well as the current donor pool

No policy language will be affected; this will be a programming only effort



These revisions include:

- Updating the HLA frequencies used to calculate CPRA
- The addition of the antigen C to the calculation
- The addition of a question to the waiting list to better interpret 0% default CPRA value



CPRA was fully implemented in October 2009

HLA frequencies from January 1,
 2003 through December 31, 2004

 Ethnic frequencies are based on deceased kidney donors recovered from January 1, 2006 through June 30, 2007



Update HLA Frequencies

- The HLA frequencies from a more recent time frame should be used to include HLA-C and certain alleles for which definition has improved with increased molecular typing
- The Committee proposes using frequencies calculated from data collected from January 1, 2007 through December 31, 2008



Update HLA Frequencies

- Updating the HLA and ethnic frequencies:
 - Will make the allocation process more accurate, effective and efficient
 - Will decrease likelihood that a candidate will receive a kidney offer that results in a positive crossmatch



The Addition of C to CPRA Algorithm

The current CPRA calculation uses the HLA frequencies for A, B, DR and DQ types



Rationale

- Currently more than 10,000 kidney registrations are listed with at least one
 C antigen as unacceptable
- Candidates are screened from matches but receive no additional CPRA value for their increased potential of a positive crossmatch



A CPRA of 0 could mean:

- The candidate had not been tested yet.
- The candidate is truly unsensitized and has no HLA antibodies.

The candidate does have HLA antibodies, but none that the in the judgment of the center warrants the listing as an unacceptable.



Or a CPRA of 0 could also mean:

The candidate has antibody to C and/or DP HLA antigens, which are not part of the CPRA algorithm.

The unacceptables listed are so rare that the CPRA is less than .5%, which would show as a CPRA of 0.



Problem

Each one of these scenarios describes a very different candidate but all would be shown to have a CPRA as 0.



Exploration of Options:

- The CPRA field:
 - Must contain a positive, whole number.
 - No letters or symbols
 - Cannot be left blank
 - 00 is not an option



Proposal

Add a mandatory field to the waitlist form for all kidney, kidney/pancreas and pancreas candidates.



Proposed field addition to Waitlist

"Was this candidate tested for anti HLA antibodies?"

- yes, antibodies detected,
- yes, no antibodies detected,
- no, not tested.



Impact

Currently, when presented with a candidate with a CPRA of 0, transplant professionals cannot tell if the candidate is truly unsensitized, sensitized, or not been tested

This is important information especially because of the increased use of a prospective virtual crossmatch



Questions???



Revision of the UNOS Bylaws that govern HLA laboratories



Synopsis

This proposal revises the UNOS Bylaws that apply to histocompatibility laboratories to more closely align OPTN/UNOS requirements for member laboratories with current laboratory practices.



The Problem...

The Histocompatibility Committee reviewed the documents from the **UNOS Rewrite Project pertaining** to histocompatibility (HLA) laboratories at their July 2011 meeting and identified several challenges.



At the meeting in July 2011...

The committee found areas that are not in line with current practice. They voted to make these updates within the current UNOS bylaws in an effort to improve the review process that will happen later next year within the Rewrite Project.



An Example:

Current Language

UNOS Bylaws Appendix B Attachment IIA - Standards for Histocompatibility Testing

C5.300 The laboratory must test proficiency samples in a manner comparable to that for testing clinical samples.



Proposed Revision

C5.300 The laboratory must test proficiency samples in the same manner comparable to that for testing clinical samples.



Committee Rationale for Revision

It is important that this bylaw be changed because this is a CLIA standard and must be adhered to.



Affected/Proposed Bylaws:

Attachment II to Appendix B of the UNOS Bylaws – Criteria for Histocompatibility Laboratory Designation

- Key Personnel Qualifications
- A.1. Director Credentials
- A2. Director Candidates
- B.1. Responsibilities of a Director of a Histocompatibility Laboratory



Affected/Proposed Bylaws:

Attachment IIA to Appendix B of the UNOS Bylaws -Standards for Histocompatibility Testing

C5.000 Proficiency Testing and Competency Evaluation

C9.000 Subcontracting

F2.000 HLA Typing

F3.000 Antibody Screening

I ABO Blood Group Determination

J Chimerism Analysis



Affected/Proposed Bylaws

Attachment IIB to Appendix B of the UNOS Bylaws; UNOS Test Data Criteria for New HLA Laboratories Data...



Questions?

